

# Maryland Board Of Pharmacy Public Meeting – August 16, 2000

The Public Meeting was called to order at 8:45 a.m.

## **ATTENDANCE**

Commissioners Present: President, Stanton Ades, Secretary W. Irving Lottier, Treasurer Melvin Rubin; Commissioners Laura Schneider, Wayne Dyke, John Balch, Raymond C. Love, Ramona McCarthy-Hawkins

Board Members Absent: Jeanne Gilligan Furman, Barbara Faltz Jackson, Reverend William E. Johnson, Sr., Donald K. Yee

Board Counsel: Paul Ballard, Linda Bethman

Board Staff: Michelle Andoll, Pharmacy Compliance Officer, James Slade, Legislative/Regulatory Officer, Deitra M. Gale, Compliance Specialist; Tamarra Banks, Network & Information Services

Guests: Howard Schiff, Catherine Putz, Geraldine Valentino, Laura Borde, Diane Darvey, Elizabeth Pujolas, Nora Schindel, Eric Yospa, John Murphy, Randy R. Delkar, Jennifer C. Murphy

## **INTRODUCTION**

President Ades asked each of the guests present to introduce him or herself. President Ades stated that due to the absence of Executive Director LaVerne Naesea, he would be responsible for the Executive Director report.

## **RECUSALS**

No one felt it necessary to be recused due to conflicts of interest.

## **APPROVAL OF MINUTES**

The following corrections were made to the minutes: pg.1, Reverend William Johnson was added as Commissioner absent.

## **PRESIDENT/EXECUTIVE COMMITTEE REPORT**

### **Crisis in Pharmacy Task Force Legislation**

Board members asked about the status of legislative request for a Task Force on the Crisis in Pharmacy Manpower, which was formally submitted by the DHMH. Mr. Slade noted that the Board is still awaiting approval of the proposed legislation from Governor's Office. He indicated that copies of the Board's submission are available.

### **Legislative Committee**

President Ades announced that the Legislative Committee would consist of himself, Melvin Rubin, Jeanne Furman, Jim Slade and Ms. LaVerne Naesea.

### **Technology & Automation Committee**

Mr. Ades announced the formation of the Technology & Automation Committee that would oversee the Board's website, Internet licensing, and automated services offered to the public. Members include: Tamarra Banks, Vladimir Konstantinov, Doris Thomas, Ramona McCarthy-Hawkins, LaVerne G. Naesea, Reverend William Johnson, and Melvin Rubin.

Ms. Banks explained that legislation approved in the fiscal year 2000 Legislative Session requires State agencies to provide 50% of their services to the public over the Internet by fiscal year 2002, and 80% by fiscal year 2004. Copies of the legislation, HB274, will be made available to the Committee members as part of their first order of business. Ms. Banks stated that the Board's web site currently offers

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pharmacist and establishment applications and instructions, pharmacy rosters, labels, complaint forms, examination applications and information online. The only services not offered online are those requiring a method of payment.

The Department is recommending that the licensing Boards and Commissions use a program called "License 2000" to provide Internet licensing, a disciplinary tracking function and a revenue collection system to comply with HB274. Ms. Banks stated that the Department estimates the system will cost \$184,000 over a three-year period, excluding maintenance and software licensure fees. The National Association of Board of Pharmacy (NABP) announced an Internet Licensure system at its convention in Tennessee last spring. NABP's system would provide pharmacist licensure, verification of continuing education and credit card processing free of charge to all state pharmacy boards. Ms. Banks indicated that she is currently investigating NABP's new licensure system, which is expected to be available in the spring of 2001.

The Committee would also provide oversight for the Board's web site. Ms. Banks noted issues concerning various agencies that currently have web sites. There is concern that the information presented on sites may not be legal and/or appropriate. The Department, in response to this concern developed guidelines recently. The Department wants each agency to have a Web Committee, which will review all postings to web sites and ensure the agencies adherence to Department Web Site Guidelines.

## EXECUTIVE DIRECTOR'S REPORT

### **Strategic Planning Committee Report (Tentative Retreat Agenda) – James Slade**

The tentative agenda for the Strategic Planning Retreat was included was the Board packet. Prior to the retreat, two forums will be held on September 13, 2000: one for the pharmacy industry, one for consumer groups.

### **Board/Staff Retreat – James Slade**

The location has not been selected as of Friday, August 11, 2000. The Board is still waiting for responses from 4 of the 6 potential vendors. If no favorable responses are received, the bids may have to be resubmitted or the retreat held locally.

### **Staffing Updates – James Slade**

A request has been denied to upgrade the Office Secretary III position to Administrative Officer I. The Board has received resumes for the Office Secretary III position and will be interviewing soon.

### **NABP District II Annual Meeting – James Slade**

Michelle Andoll and LaVerne Naesea will attend the meeting scheduled on October 19-21, 2000 in Short Hills, New Jersey. Executive Director Naesea was asked to select a topic for her or her designee to speak on. Commissioner Furman will also be attending. The Board members were asked to submit by the following Wednesday, a topic on which she or other attending Board representatives should speak at the meeting.

### **Board Reappointments – James Slade**

Board President Stanton Ades and Licensing Committee Chairman Wayne Dyke have been re-appointment to second terms, from 2000 to 2004.

## **BOARD COUNSEL REPORT – Paul Ballard**

Linda Bethman summarized the meeting with the Consumer Protection Division regarding on-line prescribing. Board representatives met with Jennifer Pressman and Ms. Wittig of that agency to establish dialogue regarding the enforcement of appropriate practices by Internet pharmacies. Executive Director Naesea, Pharmacy Compliance Officer Andoll, Licensing Supervisor Sharon Demory-Cornish, and Commissioner Melvin Rubin represented the Board. It was decided that Consumer Protection will take the lead on investigating all complaints since they have more resources available. This does not preclude the

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Board from also investigating, as it deems appropriate. The Board may refer, at its discretion, any complaints involving Internet pharmacies to Consumer Protection. Consumer Protection will contact Ms Demory-Cornish regarding any licensing issues that they may have. If an Internet pharmacy does not have a valid license, there would be grounds for prosecution. Ms Pressman requested a chart of drug contraindications to aid them in creating patient profiles in preparation for making undercover buys. This has been sent to them. The Consumer Protection Division anticipates making a 'buy' in about a month. If actions are taken, Ms Naesea will provide an affidavit or testify regarding the permit/licensing issue. A summary of the meeting is provided in the Board packet.

Michelle Andoll added that Consumer Protection asked the Board to consider requiring that the full name of the prescriber be placed on the label of prescriptions to aid in identifying prescribing physicians. Those present from the Board expressed concern about overcrowding the label. Consumer Protection also suggested that the Board use surplus funds to increase the number of investigators at the Board to investigate online pharmacies.

Tamarra Banks added that Ms Naesea had approached her about having the Technology Committee investigate Internet surveillance software, so that the Board may take a more proactive role in locating unlicensed Internet pharmacies. Linda Bethman indicated that she can provide information for Ms Banks regarding this type of software.

## **LEGISLATIVE OFFICER REPORT - James Slade**

### **Update on Legislation**

The Environmental Matters Committee requested that the Board of Pharmacy meet with BPQA to certain issues with respect to labeling. The two issues concern the indication of the condition for which the drug is prescribed and a notation on the label when the drug is a generic equivalent, which was the intent of HB 783. The Board has been asked to compile advantages, disadvantages and barriers to implementation of these potential requirements and to forward a report to the Legislative Committee by October 1, 2000. Commissioner Rubin said that this is an excellent idea but that the only way it could be done is for the physician to include the condition or diagnosis on the prescription. Without that information, the pharmacist could not be sure of the use of the drug. Howard Schiff indicated that this requirement, if enacted might be a roadblock to filling some prescriptions. President Ades mentioned that the impact on the pharmacist must be considered. Commissioner Love added that in the case of prednisone, there is a wide scope of uses for the drug. Geraldine Valentino recommended including the FDA's response in the report regarding issues relating to labeling technology.

### **Update on Regulations**

A regulations status sheet was included in the Board packet. The Unlicensed Personnel Regulations should be published September 22, 2000 in the Maryland Register. The Board is awaiting comments from NACDS related to the Closure of Pharmacies Regulations. The Automation Regulation proposal generated comments from NACDS and Board Counsel Paul Ballard.

**GUEST PRESENTER(S)** None

## **COMMITTEE REPORTS**

**Pharmacy Practice Committee - Ray Love**

### **Committee Minutes**

The Pharmacy Practice Committee met on August 2, 2000. Minutes were provided to the Board.

### **Automation Task Force**

On a question of whether the Board should restrict access to 'supplies' in Automatic Medication Dispensing Systems, the Committee decided to eliminate language about supplies.

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The Board of Nursing requested that the Board be more restrictive on the issue of replenishing and refilling the AMDS. The Committee is considering additional language.

The addition of a new section related to CDS substances will be considered.

Paul Ballard suggested that the phrase “peer review committee” be changed to “committee of the Board” because of other statutory references to a peer review committee.

On a question of whether the language causes automatic counting machines to be covered by the proposed regulations, the Committee and the Board do not intend to regulate counting machines and feel that the wording does not imply such.

It was mentioned that exceptions are allowed to the requirements for a pharmacist to review prescriptions before dispensing, if an automated robotic system has adequate QA procedures in place.

## **Outsourcing**

The Committee reported that there may be a potential conflict with the proposed regulations and the Transfer of Prescription regulations. The Committee is looking into the possibility of incorporating the outsourcing provisions into the existing transfer regulations.

## **Portable Drug Kits**

Ammonia inhalants may be added to the list of medicines allowed in the kits since no evidence was found that ammonia inhalants may cause a problem.

## **Unlicensed Personnel Task Force**

Commissioner Rubin recommended that the Board reconvene the Unlicensed Personnel Task Force as a Committee to examine the possibility of developing a category of personnel, possibly called ‘pharmacy technicians,’ who would be required to meet specific educational requirements to allow them to perform tasks that Unlicensed Personnel cannot perform at this time. They could be registered, certified, and/or licensed. Commissioner Dyke suggested checking with other states that license technicians to examine their policies. Dr. Love moved that the Board reconvene the Unlicensed Personnel Task force as a committee of the Board. Commissioner Hawkins seconded the motion and the motion was passed.

## **Prescription Requirements for Oxygen**

The Pharmacy Practice Committee will review the existing requirement that suppliers of oxygen and other gases have Distribution Permits from the Board.

## **Prescriber’s Name on Label**

On the issue of requiring the full name of the prescriber on the prescription labels, as requested by the Consumer Protection Agency, the Board is hesitant to require this information at this time. As to the current requirement that the prescriber’s name be legible, the Board decided to ask the Board of Physician Quality Assurance to emphasize this requirement to physicians.

## **Internet Pharmacies**

The Board discussed the role it should play in investigations and what resources would have to be available to the Board. The recommendation was made that the committee having oversight over our Website develop a way to educate the consumer about Internet sites and precautions they should take. Information is available from NABP and the FDA describing the information needed to determine that a site is practicing pharmacy appropriately. The Board suggested listing links to those sites.

## **Licensing Committee - Wayne Dyke**

### **Committee Minutes**

The Licensing Committee met on July 26, 2000 and August 9, 2000. The Commission for Certification in Geriatric Pharmacy requested that the Board accept pharmacists who have passed their certification examination as having met the Board’s Continuing Education requirements without having to document the courses that were taken in preparing for the examination. The Committee recommended

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sending a letter requiring documentation of preparation for the examination and a certificate of attendance in order for these candidates to receive CE credit.

A request for a waiver of the requirement to pass the FPGEE examination was received from a candidate for licensure who graduated from a pharmacy school in Nigeria and is licensed in Cameroon. NABP requires that an applicant be licensed in the country in which they earned their degree, but Nigeria will not allow citizens of other countries to sit for the licensure examination in Nigeria. The Board is unable to grant the request.

A request for a waiver from having to take the Jurisprudence Examination and the English competency exam was denied.

In order to streamline the approval of continuing education programs, the Board decided to approve programs beginning in the month they are first approved, rather than beginning the first of the year in which they are approved. ACPE approved programs will be listed on our Web Site. A request was received from one of our delegates in Annapolis, seeking C.E. credits for hearing bills in the Maryland legislature, and for the Board to consider allowing credits for pharmacists who perform community actions such as speeches to senior citizens and 'brown bag' sessions. The Licensing Committee will examine other activities may be considered for some credits. The Committee will also look into the possibility of requiring specific numbers of credits in specific areas.

The Board agreed with the Licensing Committee proposal to send letters to licensure candidates who have not completed all requirements for licensure, sixty days after they have completed the Laboratory Examination. They will be notified of the scores received and which segments the Board has not yet received. Some candidates have waited for a long period of time after becoming eligible, to take the NAPLEX and/or MPJE examinations. The notice will alert candidates to the Board's current records of their examination results. Currently the Board only notifies candidates who fail a segment or those who have passed all examinations including Oral Competency. Scores will be listed on the Website by candidate number as soon as possible after they are received.

### **Reciprocity - List of Candidates**

The Licensing Committee held their reciprocity meeting on August 15, 2000. Commissioner Dyke read the names of the reciprocity candidates. All have satisfied the requirements except one who is pending the oral competency portion. Mr Dyke moved that the candidates be approved for licensure. The motion was seconded by Ramona Hawkins and passed by the Board.

### **Closure of Pharmacies – James Slade**

Mr. Slade is waiting for comments from NACDS on the proposed regulations which are intended to streamline the closing of pharmacy procedures. A change was made in the proposal which now will require that permit holders request their closing inspection within 72 hours after closing.

On a request for clarification from Mr. Schiff, Mr. Slade said that the request must be "documented," which could mean that although Drug Control can merely document the request, a written request from a permit holder is preferable. Mr Ballard noted that, according to the language, the documentation must be within 72 hours before *or* after the date, so that holidays and weekends should not be an issue..

### **Practical Exam Component**

A discussion was held relating to the necessity of the wet lab component of the Examination. Committee members were asked to present sample questions to the next Board meeting.

### **PEAC (Pharmacists Education and Assistance Committee)**

#### **Update – Randy Delkar**

Mr Delkar, a member of the pharmacist rehabilitation committee, reported that there are currently 25 active cases with 2 new cases pending psychiatric evaluations.

A Retreat was held in July, with discussions concerning ways to recruit additional monitors, improving relationship with the Board and various treatment programs, and establishing a student rotation which is expected to be implemented in the Fall. PEAC thanked the Board for their financial support.

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Plans are finalized for developing a web site. Melvin Rubin and LaVerne Naesea attended the retreat. Ms Naesea was concerned regarding PEAC's frequent requests to end probation before the Board ordered date.

## **Public Relations Committee/Council of Boards Report – Tamarra Banks**

### **Web Site Statistics**

This information was included in the Board packet.

### **Media Campaign**

The Postcard Campaign started slowly, but postcards are now being distributed by 217 pharmacies across the State. Many pharmacies are unaware of the Postcard Campaign encouraging consumers to "Talk To Your Pharmacist", however, the Board continues to communicate this information through letters and telephone calls. The Division of Drug Control has been distributing postcards to pharmacies while performing inspections and Howard Schiff has offered to contribute address information for community pharmacy owners who are members of his association. The Reeves Agency will restart the Media Campaign radio message during October to increase awareness in Seniors and their caregivers again.

### **ASCP Convention**

The Convention will be held Friday, August 18, 2000 and Saturday August 19, 2000 in Rocky Gap, Maryland. John Balch and Jeanne Furman will be attending. The Board of pharmacy will maintain a booth, which will focus on senior citizens and their caregivers.

### **NPhA Conference**

The National Pharmaceutical Association Conference was held July 21 - 25<sup>th</sup> in Baltimore. Those attending from the Board included Commissioners Jackson, Dyke and Hawkins, and staff members LaVerne Naesea, Sharon Demory-Cornish and Michelle Andoll. The focus of the booth was on licensure in Maryland.

### **Consumer-Related Activities**

The Board may participate in the Senior Expo in October at the Timonium Fairgrounds.

### **National Pharmacy Week**

The Committee is working on an event called the "Traveling Medicine Show," to take place October 22 to 28 during National Pharmacy Week. The Board, in conjunction with other pharmacy related organizations will travel to different pharmacies throughout the State during that week providing "Brown Bag" consulting, opportunities to talk to a pharmacist and promotional items. The Committee intends to host the Medicine Show in 6 different locations.

## **Budget Committee – Irv Lottier**

Mr. Lottier reviewed the FY 2000 budget and the FY 2002 proposed budget, as well as the contract tracking record. All applicable documents were included in the Board packet.

## **Question(s) for the Board**

### **Family Pharmacy Request for Two Licenses in One Location – E. Yospa, Guest**

The Board received a request from a pharmacy to issue two pharmacy permits. The permit holder, Eric Yospa wants to maintain his compounding business separate from the other portion of the practice due to a possible pending sale of the pharmacy. John Murphy, Mr. Yospa's co-worker, also spoke on his behalf. Mr. Ades recommended that Mr. Yospa submit an application. Dr. Love added that he should include in writing sufficient information to address the concerns of the Board members. The general feeling is that two licenses should only be issued for one location if different populations are being served (such as, ambulatory and long-term care). Since a full service permit requires that all reasonable prescriptions be filled, that entity could not refuse to fill compounded prescriptions and both pharmacies could serve the same population.

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## **Use of Surplus Funds to Monitor On-line Pharmacies – James Slade**

Ms Naesea asked the Board to consider asking the Legislature whether it can use some of its' surplus funds to finance the investigation process for online pharmacies, as requested by Consumer Protection. The Board requires additional details before making a decision regarding this request.

## **Distribution of Certain Medical Devices – Michelle Andoll**

The Board discussed the requirements for distribution permits to sell certain medical devices and oxygen. The Board will seek information from the FDA regarding how oxygen, other gasses and some medical devices are classified and the intent and meaning of the statement 'may be sold on authorization of a physician' as opposed to the Federal Caution Statement that indicates a product may not be sold without a prescription.

## **Costco Pharmacy**

Costco has a policy which allows the offering of pharmacy services to non-members of the Price Club. State law requires that pharmacies operating without waiver permit service all patients. A former member, who was allegedly banned for shoplifting, is demanding to be allowed into the establishment to obtain prescriptions, but Costco is denying entrance to her. The pharmacist asked if he was required to serve this patient. Ms. Andoll will inform the pharmacist that he can deny service, but is obligated to transfer the patient's prescription.

## **Informational**

### **Portable Drug Kit Update – Michelle Andoll/James Slade**

The Joint Committee of Nursing and Pharmacy will meet again in September to finalize the list of medications which may be contained in the kit.

### **NHIA 10<sup>th</sup> Annual Conference (2/20-2/23/01)**

This is an information item included in the packet.

## **Follow - Up Letters/Meetings**

### **Letters to Pharmacy Industry and Consumer Groups Regarding Public Forums (Strategic Planning Activity)**

Copies were included in the Board packet.

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